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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,195	10/30/2003	Eric M. Leproust	10030416-1	3542
22878 7590 12/31/2007 AGILENT TECHNOLOGIES INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.			EXAMINER	
			SIMS, JASON M	
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			NOTIFICATION DATE	DELIVERY MODE
			12/31/2007	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

	Application No.	Applicant(s)			
	10/698,195	LEPROUST ET AL			
Office Action Summary	Examiner	Art Unit			
	Jason M. Sims	1631			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on <u>02 O</u>					
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· — · · ·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims		•			
4) ☐ Claim(s) <u>1-10,13-15,22 and 24-31</u> is/are pendidal 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) <u>1-10,13-15,22 and 24-31</u> is/are reject	vn from consideration.				
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct	epted or b)  objected to by the l drawing(s) be held in abeyance. See	∋ 37 CFR 1.85(a).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No.</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate			

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#### **DETAILED ACTION**

Applicant's arguments, filed 10/2/2007, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 10/2/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant's newly added claims 30-31 in the response filed 10/2/2007 have been acknowledged and entered.

Claims 1-10, 13-15, 22, and 24-31 are the current claims hereby under examination.

## Claim Rejections - 35 USC § 112

## Response to Arguments:

Applicant's arguments, filed 10/2/2007 with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicants amendment. Therefore the rejection has been withdrawn.

# Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 22, 24-29, and 31 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete,

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and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc.

CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to <u>9</u> -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, <u>31 USPQ2d 1754, 1757-58</u> (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, <u>31 USPQ2d at 1557</u>. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be

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"tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-10 22, 24-29, and 31 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or to a user, or by including a final resulting step of a physical transformation, if such wording is supported by the instant specification.

## Response to arguments:

Applicant's arguments filed 10/2/2007 with respect to the rejection of claims 1-10, 22, and 24-28 have been fully considered but they are not persuasive.

Applicant argues that the examiner did not first determine whether the claims cover a judicial exeception.

Applicant's arguments are not found persuasive as the requirement concerning a judicial exception is to first determine whether the claims meet a judicial exception *OR* a practical application of a judicial exception:

The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., Rubber-Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498, 507 (1874) ("idea of itself is not patentable, but a new device by which it may be made practically useful is");

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Mackay Radio & Telegraph Co. v. Radio Corp. of America, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."); Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of locating' a medial axis, and creating' a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic abstract idea"). Therefore if USPTO personnel determine that it is more likely than not that the claimed subject matter falls outside all of the statutory categories, they must provide an explanation. For example, a claim reciting only a musical composition, literary work, compilation of data, >signal,< or legal document (e.g., an insurance policy) per se does not appear to be a process, machine, manufacture, or composition of matter.

USPTO personnel must ascertain the scope of the claim to determine whether it covers either a 35 U.S.C. 101 judicial exception or a practical application of a 35 U.S.C. 101 judicial exception. The conclusion that a particular claim includes a 35 U.S.C. 101 judicial exception does not end the inquiry because the practical application of a judicial exception may qualify for patent protection.

In the instant application, the claims have been found to be a practical application of a judicial exception because they comprise computational steps which attempt to transform matter, but do meet the statutory requirements for patentability of a practical application of a judicial exception, which are:

A claimed invention is directed to a practical application of a 35 U.S.C. 101 judicial exception when it:

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- (A) "transforms" an article or physical object to a different state or thing; or
- (B) otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

The instant claims do not transform a physical object nor produce a tangible result as discussed above. Therefore the rejection is being maintained.

## Claim Rejections - 35 USC § 103

## Response to Arguments:

Applicant's arguments, filed 10/2/2007 with respect to the rejection of claims under 35 USC 103 have been fully considered and are persuasive because of applicants statement on the record under 35 USC 103 (c). Therefore the rejection has been withdrawn.

## The following rejection is being newly made:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-7, 13-15, 22, 24-27, and 30-31 are rejected under 35 U.S.C. 103(a) as being obvious over McGall (US P/N 5,843,655) in view of Tomiuk et al. (December 2001) and further in view of Minor et al. (Pub No. US 2004/0019466).

The claims are directed to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe for a target nucleic acid, said method comprising: (a) determining a full length synthesis probability measure for each member sequence of a set of a plurality of candidate probe sequences for said target nucleic acid by evaluation of the susceptibility to depurination during synthesis of each probe sequence; and (b) employing said determined full length synthesis probability measures to select a sequence for use as a substrate immobilized probe for said target nucleic acid.

McGall teaches limitations of claims 1-7, 13-15, 22, 24-27, and 30-31 at the abstract, col. 1, lines 5-51, col. 4, lines 12-36, col. 8, lines 50-67 and col. 9, lines 1-21. McGall teaches a method for identifying sequences for use as substrate surface immobilized probes. McGall teaches testing many different sequences of candidate probes by determining susceptibility to depurination, using algorithms for comparing hybridization patterns, and using these determined values to select sequences for use as substrate surface immobilized probes. Furthermore, McGall at col. 4, teaches a method of testing as a screening and optimization process. Moreover, McGall at col. 4 and col. 8 – col. 9 discusses the use of various quality parameters for testing and screening such as an amount of deprotection of oligonucleotides and optimizing deprotection methods, which reads on a threshold parameter used for deblock doses.

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McGall at col. 8, lines 51-67, col. 9, and col. 10, lines 1-34 where it optimizing deprotection methods and susceptibility to depurination are discussed.

McGall does suggests but does not specifically teach selecting a sequence for use as a substrate. McGall suggests this limitation because a method of screening the sequences used reads on the broad intrepretation of a selection process.

Tomiuk et al. teaches this limitation throughout the invention and in particular at the abstract, page 329, paragraph 1, page 330, first column, paragraph 1 and second column, paragraphs 1-2. Moreover, Tomiuk et al. discusses at page 329, column 1, paragraph 1 how a successful microarray application requires particular conditions and prerequisites for selecting appropriate DNA probes for an situ nucleic acid synthesis where the probe sequence is selected from a set of candidate sequences. Tomiuk et al. discusses, at the abstract, page 330, first column, paragraph 1 and second column, paragraphs 1-2, probe selection strategies and the use of computer programs for the optimal choice of oligonucleotide sequence selection, which reads identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe from a set of candidate probe sequences and determining a full length synthesis probability measure via an algorithm. Furthermore, Tomiuk et al. discusses the need to pay special attention to sequence characteristics such as, for example, composition and order of bases.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use some of the parameters measured in McGall for pre-selecting

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sequences for potential use a substrate immobilized probe because one would be motivated to further optimize manufacturing success.

Claims 8-9 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGall (US P/N 5,843,655) in view of Tomiuk et al. (December 2001) as applied to claim 1-7, 13-15, 22, 24-27, and 30-31 above, and further in view of Minor et al. (Pub No. US 2004/0019466).

The combined references of McGall and Tomiuk et al. do not specifically teach a method wherein the deblock dose is a sum of individual deblock doses over all A nucleotides of said candidate probe sequence. However, McGall does teach a method of calculating optimized deblock doses for particular sequences during the testing methods.

Minor et al. at paragraph [0120] discusses how hybridization can effect the quality of an array application and how selected probes may be inferior due to degradation factors such as a depurination factor specific to a nucleotide "A" in the probe sequence content, which exemplifies the need to consider a depurination factor when identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe for a target nucleic acid. Minor et al. at paragraphs [0122], [0215] – [0256] discusses De-blocking and statistical methods for improving probe selection such as those in recited claims.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a depurination factor and deblocking as taught by Minor et al.

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for a strategy for selecting probes as taught by Tomiuk et al. because Tomiuk et al. because Minor et al. discusses the challenges with selecting probes for nucleic acid sequence synthesis for use in microarray applications where there is a need to pay special attention to sequence characteristics, such as composition and order of bases and such attention to said characteristics can greatly minimize susceptibility to depurniation during synthesis of each probe sequence. Furthermore, Tomiuk et al. teaches how using computer programs for optimal choice selection can offer the advantage that probes can be quality-controlled before the spotting process. McGall already teaches producing a nucleic acid array where the depurination is minimzed. However, it would have further been obvious to one of ordinary skill in the art at the time of the instant invention to use a depurination factor and deblocking, as taught by Minor et al. for use in a probe selection strategy, as taught by Tomiuk et al. to select a optimal sequence from a set of a plurality of probe sequences because McGall already recognizes the need for minimizing the depurination factor optimizing deblocking and it is common practice in microarray applications to have the need to select an optimal probe sequence for use, therefore, selecting a probe, which minimizes the susceptibility to depurination is selecting an optimal probe sequence for use.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

MICHAEL BORIN, PH.D PRIMARY EXAMINER